YAAKOV M. ROTH
Acting Assistant Attorney General

AMANDA N. LISKAMM
Director

LISA HSIAO
Deputy Director, Civil Litigation

JAMES W. HARLOW
Acting Assistant Director

NOAH T. KATZEN
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 305-2428
(202) 514-8742 (fax)
Noah.T.Katzen@usdoj.gov

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

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| STATE OF WASHINGTON, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,<br><br>Defendants. | No. 1:23-cv-03026<br><br>DEFENDANTS' REPLY IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT<br><br>With Oral Argument: TBD (*see* ECF No. 153) |

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## INTRODUCTION

Since mifepristone was approved nearly a quarter century ago, the drug has been subject to restrictions, or "elements to assure safe use" (ETASU). These restrictions guard against risks relating to heavy bleeding, missed ectopic pregnancy, and other issues. In December 2021, the U.S. Food and Drug Administration (FDA) found insufficient evidence to eliminate mifepristone's Risk Evaluation and Mitigation Strategy (REMS), including the ETASU, in its entirety. FDA instead directed mifepristone's sponsors to propose more limited modifications to the REMS, which were approved in 2023. *See* 21 U.S.C. § 355-1(g)(4)(B). Plaintiffs challenge that determination, but FDA's opening brief explained why the agency is entitled to summary judgment. ECF No. 170 (FDA MSJ). Plaintiffs' opposition (ECF No. 179 (Pl. Opp'n)) fails to show otherwise.

*First*, Article III's standing requirement bars most of the Plaintiffs from pursuing their claims. Of the 18 plaintiff States, 17 did not meet their burden at summary judgment to establish standing through declarations or other admissible evidence. At most, one State—Washington—has standing, based solely on the University of Washington's (UW's) compliance costs. Any relief should be limited to redressing that narrow injury, which Washington alleges it suffers only in its capacity as operator of UW's pharmacy. *Contra* Pl. Opp'n 34-35.

*Second*, Plaintiffs concede that they did not seek relief from the agency through a citizen petition as required by regulation. And they fail to establish that FDA's position "appear[ed] already set," as required to establish futility. *Vasquez-Rodriguez v. Garland*, 7 F.4th 888, 896 (9th Cir. 2021) (quoting *Szonyi v. Barr*, 942 F.3d 874, 891 (9th Cir. 2019)). For example, they have not shown that FDA would have rejected their arguments about the Canadian study, which was not even published at the time FDA decided what modifications to direct the sponsors of mifepristone to propose.

*Third*, none of Plaintiffs' Administrative Procedure Act claims survives scrutiny. FDA did not fail to consider relevant statutory factors (Pl. Opp'n 14-17) because the six factors in 21 U.S.C. § 355-1(a)(1) that Plaintiffs cite are inapplicable to a REMS modification decision. And, contrary to Plaintiffs' contentions, FDA's finding that there was insufficient evidence of safety to eliminate all of the ETASU satisfied § 355-1(f).

Plaintiffs also do not identify any relevant record evidence (Pl. Opp'n 18-26) that FDA failed to consider. The Canadian study was not published until after FDA completed its literature review and directed the sponsors to seek approval of narrower modifications. Nor was the study subsequently cited to the agency in connection with its REMS review. And while Plaintiffs criticize FDA's focus on "objective safety data" on the ground that "safety is not the only statutorily

required consideration," Pl. Opp'n 19, they do not explain how, absent a showing of safety, FDA could approve a change to a drug's conditions of approval.

Nor do Plaintiffs identify any flaw in FDA's reasoning. Plaintiffs assume that no ETASU are needed for Mifeprex (or its generic version) because none are needed for Korlym. Pl. Opp'n 27-28. But the conditions of use of Korlym are different than those of Mifeprex and its generic in important ways. Beyond that, Plaintiffs err by disregarding (Pl. Opp'n 26-27, 29-33) how FDA, in 2023, did not write on a blank slate. The agency had already determined, several times over many years, that a REMS with ETASU is necessary—decisions unchallenged by Plaintiffs. The sole final agency action at issue is the January 2023 REMS Modification, which arose from FDA's most recent REMS review. ECF No. 35 (Am. Compl.) ¶¶ 258, 262, 265. And the narrow question before FDA in that review was whether evidence post-2016 warranted a departure from earlier assessments that certain ETASU are necessary. Because Plaintiffs misconstrue the question before FDA, their attempt to undermine the reasonableness of the agency's reasoning falls short.

*Fourth*, Plaintiffs' constitutional claims (Pl. Opp'n 33-34) are baseless. As Plaintiffs concede, States have no rights under the Fifth Amendment. To avoid the consequence of that concession, Plaintiffs now assert that they have third-party standing to assert the constitutional rights of "staff and students at the University of

Washington." But the Amended Complaint lacks any allegation that Plaintiffs are suing on behalf of UW's staff and students. In any event, Plaintiffs have not shown that third-party standing would be appropriate here.

## ARGUMENT

### I. Washington Is The Only Proper Plaintiff

All Plaintiffs but one failed to establish that they are entitled to seek judicial relief in this case. "Article III controls not only who may have access to federal courts at the threshold of the litigation, but also who may obtain a judgment." *Legal Aid Soc. of Alameda Cty. v. Brennan*, 608 F.2d 1319, 1333 n.26 (9th Cir. 1979). Thus, "each plaintiff" who seeks to obtain a favorable judgment must establish standing. *Valley Forge Christian College v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982) (citations omitted). A district court cannot grant relief to any plaintiff who lacks Article III standing. *See Challenge v. Moniz*, 218 F. Supp. 3d 1171, 1179 (E.D. Wash. 2016) (Rice, J.). Instead, the court "must . . . narrowly tailor[] [the] remedy [to] the specific harm shown" by plaintiffs who have established standing. *City & Cnty. of S.F. v. Trump*, 897 F.3d 1225, 1244 (9th Cir. 2018) (quoting *Bresgal v. Brock*, 843 F.2d 1163, 1170-71 (9th Cir. 1987)); *see also Gill v. Whitford*, 585 U.S. 48, 73 (2018) ("'[S]tanding is not dispensed in gross': A plaintiff's remedy must be tailored to redress the plaintiff's particular injury.") (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006)).

Here, no Plaintiff other than Washington has met its burden at summary judgment to prove standing through "affidavit[s] or other evidence." *Arakaki v. Hawaii*, 314 F.3d 1091, 1098 (9th Cir. 2002) (internal quotation marks omitted). Sixteen Plaintiffs—Arizona, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland,[1] Michigan, Nevada, New Mexico, Rhode Island, Vermont, Hawaii, Minnesota, Pennsylvania, and the District of Columbia—offered no evidence whatsoever on standing, even though it is "an indispensable part of [their] case." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

A seventeenth Plaintiff, Oregon, also failed to carry its standing burden. Oregon "join[ed]" this suit solely "in its capacity as parens patriae," Am. Compl. ¶ 17, a legally invalid theory that Oregon appropriately abandons. *See* FDA MSJ 12 (citing *Murthy v. Missouri*, 603 U.S. 43, 76 (2024); *Washington v. FDA*, 108 F.4th 1163, 1177 (9th Cir. 2024)). Instead, Plaintiffs now cite four paragraphs of declarations by persons affiliated with the Oregon Health & Science University (OHSU). Pl. Opp'n 5, 6, 8. However, nowhere in the Amended Complaint did

[1] Although, at the preliminary-injunction phase, Maryland submitted a declaration by a private practitioner, Nelson Decl., ECF No. 62, it established no injury to the State and was not cited in Plaintiffs' summary-judgment opposition, *see* Pl. Opp'n 2-9.

Oregon assert standing based on injuries to that or any other state institution. Am. Compl. ¶¶ 189-198; *see also La Asociacion de Trabajadores de Lake Forest v. City of Lake Forest*, 624 F.3d 1083, 1089 (9th Cir. 2010) (holding that a plaintiff "may not effectively amend its Complaint by raising a new theory of standing in response to a motion for summary judgment"). And in any event, none of these paragraphs establishes any injury to OHSU. Nichols Decl., ECF No. 4-1, ¶ 38 (referring to "burdens and stresses on patients and providers" generally); Colwill Decl., ECF No. 4-1, ¶¶ 19-20 (purporting to describe REMS requirements and alleging that they impede patients' access to mifepristone); *id.* ¶ 24 (alleging that the REMS can injure patients). Thus, Oregon lacks standing.

As for Washington, it has not proven any injury requiring statewide relief. It, too, abandons its *parens patriae* theory. And its theory based on alleged healthcare costs is too attenuated, speculative, and unsupported to satisfy Article III. *See FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 390-91 (2024). Contrary to Washington's assertions (Pl. Opp'n 7), its alleged healthcare costs do not result from "direct" regulation by the REMS. Rather, those costs allegedly result *indirectly* from patients' decisions to opt for surgical abortion or remain pregnant. Pl. Opp'n 6 (arguing that patients eschew mifepristone in favor of more expensive options and pass those costs on to the State). And Washington does not identify any

evidence establishing that the challenged agency action causes more patients to choose a care option that is more expensive to the State.[2]

At most, the evidence shows an injury to Washington in its capacity as the operator of UW's pharmacy, due to the ongoing costs of complying with the pharmacy certification requirement. *See* FDA MSJ 14. Thus, Washington lacks standing to seek any relief beyond what would redress the UW's alleged injuries. *Gill*, 585 U.S. at 73; *Cty. & Cnty. of S.F.*, 897 F.3d at 1244; *Bresgal*, 843 F.2d at 1170-71.

**II. Plaintiffs Failed To Administratively Exhaust Their Claims**

To evade FDA's exhaustion argument on futility grounds, Plaintiffs had to show FDA's position on evidence and arguments not raised during the administrative process "appears already set." *Vasquez-Rodriguez*, 7 F.4th at 896 (quoting *Szonyi*, 942 F.3d at 891). Yet the opposition, for example, does not

[2] Fearing that another court would restore more restrictive REMS requirements, Washington's declarants anticipated an "increase" in the States' current costs from REMS restrictions. Birch Decl., ECF No. 4-1 ¶¶ 10, 17. Fontinos Decl., ECF No. 4-1 ¶¶ 10, 14, 15. As the future tense makes clear, these statements were about the restrictions Plaintiffs thought would be restored, not the January 2023 REMS modification—which *reduced* restrictions on mifepristone.

demonstrate that FDA would have rejected the claim that the Canadian study provides "objective safety data" that mifepristone is safe without ETASU. As explained below, FDA did not consider that study, published after FDA decided what modifications to direct the sponsors to propose. Indeed, the study was never provided to the agency until after the sponsors submitted their supplemental applications proposing the more limited modifications directed by FDA.

Plaintiffs respond that FDA could have halted its review of those supplemental applications and reopened the question of what modifications to request based on the Canadian study. Pl. Opp'n 13. FDA was not required to do so. *See infra* pp. 13-14. In any event, whether FDA *could* have done so is irrelevant for assessing futility: FDA *did not* consider the Canadian study, and thus its position could not have been "already set."

## III. Plaintiffs' APA Arguments Are Meritless

If the Court reaches the merits, Plaintiffs' APA claims are unavailing.

### A. FDA considered all relevant statutory factors

As FDA explained, the applicable REMS modification standard is set forth in 21 U.S.C. § 355-1(g)(4)(B). *See* FDA MSJ 18, 26. Plaintiffs accuse FDA of failing to consider other factors, *see* Pl. Opp'n 14-17, which either were irrelevant or already considered by FDA.

**The § 355-1(a)(1) factors.** Plaintiffs err in contending that FDA was required to consider the six specific factors in 21 U.S.C. § 355-1(a)(1). Pl. Opp'n 14-16. That provision governs FDA's initial decision to require the sponsor of a pending application to propose a REMS. But "[a]fter the approval of a" REMS, the operative framework is supplied by 21 U.S.C. § 355-1(g)(4)(B), under which FDA "may" require the sponsor of the drug to "submit a proposed modification" if, as relevant here, FDA "determines that 1 or more goals or elements should be added, modified, or removed" to (1) "ensure the benefits of the drug outweigh the risks of the drug" or (2) "minimize the burden on the health care delivery system of complying with the strategy." 21 U.S.C. § 355-1(g)(4)(B).

On its face, § 355-1(g)(4)(B) neither cross-references nor contains the factors from § 355-1(a)(1). "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983). Although FDA must make an "assessment" of whether evidence supports departing from the agency's conclusion that "the drug's risks require [a] REMS," *Washington v. FDA*, 668 F. Supp. 3d 1125, 1140 (E.D. Wash. 2023), in so doing, FDA need not consider factors nowhere mentioned in 21 U.S.C. § 355-1(g)(4)(B).

Other textual signs also point against reading the subsection (a)(1) factors into subsection (g)(4)(B). Both the heading to subsection (a)(1) and the only cross-reference to subsection (a)(1) in § 355-1 describe it as applying to an application for "initial approval." *See* 21 U.S.C. § 355-1(h)(3). Whereas subsection (a)(1) governs *before* approval, when the REMS is still "*proposed*," *id.* § 355-1(a) (emphasis added), subsection (g)(4)(B) applies "*[a]fter the approval* of a [REMS]," 21 U.S.C. § 355-1(g)(4)(B) (emphasis added). What is more, Congress recognizes the distinction between modification decisions and initial approval decisions by providing different dispute resolution procedures for each. *See* 21 U.S.C. § 355-1(h)(3)-(4). Finally, the factors in subsection (a) are crafted in language that more naturally applies to drugs that have not previously been marketed for a particular use subject to a REMS. FDA MSJ 26-27 (discussing 21 U.S.C. § 355-1(a)(1)(A)-(F)).

Searching for a way to import the factors from § 355-1(a)(1) into § 355-1(g)(4)(B), Plaintiffs suggest that the phrase "ensure the benefits of the drug outweigh the risks of the drug" (which appears in both provisions) somehow *means* the six factors in § 355-1(a)(1). Pl. Opp'n 14-15. But ensuring that the benefits of the drug outweigh the risks of the drug is not a REMS-specific concept: FDA *always* considers drug safety in its approval process. FDA Guidance for Industry, *Benefit-Risk Assessment for New Drug and Biological Products* (Oct.

2023) (explaining that in determining safety FDA examines whether "the benefits of the drug outweigh its risks").[3] Congress did not require consideration of the § 355-1(a)(1) factors in *every* safety analysis, but just in one specific context: an initial decision whether to direct a drug sponsor to propose a REMS. Thus, this case does not implicate (as Plaintiffs contend) a need to give the same statutory term a consistent meaning throughout the statute, Pl. Opp'n 14; the applicable rule is that courts should give *different* statutory language a *different* meaning. *See Russello*, 464 U.S. at 23.

**The § 355-1(f) factors.** Plaintiffs also go astray when accusing FDA of not considering the safety and burden factors set forth in § 355-1(f). Pl. Opp'n 16-17. FDA made the required statutory findings.

The agency can approve a supplemental application modifying a REMS only if the evidence shows the drug will be safe (i.e., the benefits will outweigh the risks) with the modification. 21 U.S.C. §§ 355-1(g)(4)(B), 355(d); 21 C.F.R. §§ 314.1 (providing that new drug application requirements apply to supplemental applications), 314.105(c); *see also* FDA Guidance for Industry, *Benefit-Risk Assessment for New Drug and Biological Products* (Oct. 2023). Here, FDA found

[3] Available at https://www.fda.gov/media/152544/download (accessed May 30, 2025).

insufficient evidence to demonstrate that mifepristone's benefits would outweigh its risks if the REMS with ETASU were eliminated. EAR164, 167, 186. In other words, the ETASU are "necessary . . . to mitigate" mifepristone's risks, mifepristone "can be approved only if, or would be withdrawn unless" ETASU remained part of the drug's conditions of approval, and the ETASU are "commensurate with" mifepristone's risks. 21 U.S.C. § 355-1(f)(1)(A), (2)(A). Additionally, the ETASU do not unnecessarily burden patient access, *id.* § 355-1(f)(2)(C), (D), since FDA had insufficient evidence to approve the drug without the ETASU.

**Harmless error.** For the same reason, any failure to consider a relevant statutory factor was harmless. 5 U.S.C. § 706 ("[D]ue account shall be taken of the rule of prejudicial error."); *FDA v. Wages & White Lion Investments, LLC*, 145 S. Ct. 898, 930 (2025) ("When it is clear that the agency's error 'had no bearing on the procedure used or the substance of [the] decision reached,' a remand would be pointless.") (quoting *Mass. Trustees of E. Gas & Fuel Assoc. v. United States*, 377 U.S. 235, 248 (1964)). Plaintiffs brush aside the harmless-error point as "self-serving." Pl. Opp'n 17. But they never address the crux of the matter: Because FDA found insufficient evidence of safety to eliminate the ETASU, the agency could not approve a supplemental application without the ETASU. 21 U.S.C. § 355(d).

**B. Plaintiffs identify no relevant record evidence that FDA did not reasonably consider**

Next, Plaintiffs have not shown that FDA failed to reasonably consider the relevant record evidence when assessing whether evidence since 2016 demonstrated that the ETASU could be eliminated. EAR159, 162, 166.

**The Canadian study.** As FDA explained (FDA MSJ 17-18, 31-32), the Canadian study (EAR238) was not before FDA when it conducted the comprehensive literature review or directed mifepristone's sponsors to propose certain modifications to the REMS. Nor did anyone urge FDA to consider that study in connection with the decision under review in this case. Instead, the Canadian study was submitted to FDA in October 2022 as part of a citizen petition that requested a different agency action and made arguments outside the scope of Plaintiffs' claims. Plaintiffs cite no authority supporting their contention that the APA nonetheless required FDA *sua sponte* to pluck the study out of the record in a different proceeding and consider it here.

Plaintiffs respond that FDA knew about the Canadian study before it approved the supplemental applications in January 2023. Pl. Opp'n 24. That is beside the point. FDA reasonably imposed a cut-off date for its literature review for administrability purposes. Otherwise, a final decision could be endlessly delayed while FDA refreshed the literature review to account for new studies published in the year-long interval between directing sponsors to propose modifications to the

REMS and approving those modifications. *Cf. Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 554–55 (1978) ("there would be little hope that the administrative process could ever be consummated" if an agency were required to consider any evidence that arrives in the "gap between the time the record is closed and the time the administrative decision is promulgated") (quoting *ICC v. Jersey City*, 322 U.S. 503, 514 (1944)).

To be sure, FDA reviewed certain materials after the cut-off date when those materials came to its attention *in connection with its review of the proposed modifications*. But, importantly, FDA at that time focused on whether to approve the sponsors' supplemental applications—not on whether to restart the process and reevaluate whether to request modifications it did not request in December 2021. For example, FDA reviewed materials attached to the November 2022 complaint in *Alliance for Hippocratic Medicine v. FDA*, 22-cv-223-Z (N.D. Tex.) (now *Missouri v. FDA*), in which plaintiffs claimed, among other things, that the in-person dispensing requirement remained necessary—an issue that went to FDA's forthcoming January 2023 REMS Modification. SEAR75-78. The published Canadian study, by contrast, was not cited in any challenge to that forthcoming action.

**Other evidence.** FDA appropriately considered the remaining evidence, focusing primarily on "objective safety data," FDA MSJ 30-31—that is,

"publications containing safety data related to the outcomes of medical abortion," 2021 REMS 001571. Plaintiffs identify no "objective safety data" before the agency in December 2021 that FDA did not review. Instead, Plaintiffs allege that FDA failed to consider various advocacy and position statements, "'stakeholder' feedback," surveys, and qualitative studies. Pl. Opp'n 19-22. But as FDA previously explained, the agency considered the material but generally found it not informative to the safety analysis. FDA MSJ 34-35; *cf. FCC v. Prometheus Radio Project*, 592 U.S. 414, 426 (2021) ("The FCC did not ignore the Free Press studies. The FCC simply interpreted them differently."). Plaintiffs respond that "safety is not the only statutorily required consideration in a REMS review." Pl. Opp'n 19. But since safety is a requirement for approving a modification, *see supra* pp. 11-12, it was reasonable for FDA to focus on that issue.

**C. FDA reasonably explained its decision**

FDA's decision not to initiate elimination of the ETASU—and its explanation for that decision—was eminently reasonable considering the context. The 2021 REMS review occurred against the backdrop of prior determinations that mifepristone's benefits had not been shown to outweigh its risks without ETASU. Those include FDA's approval decision in 2000; Congress's decision in 2007 to "deem" existing restrictions on drugs such as mifepristone to be an approved REMS with ETASU; and FDA's affirmation in 2011 and 2016 that the

mifepristone ETASU could not be eliminated.

In 2021, FDA simply addressed whether evidence generated since the 2016 review justified the elimination of all of the ETASU. In a 40-page memorandum, EAR150-98, FDA explained that the required showing had not been made because the evidence—primarily "objective safety data"—did not provide the agency with the assurance it would need to change its baseline assessment and remove all restrictions. Proceeding ETASU by ETASU, FDA discussed the rationale for its decision to require pharmacy certification and maintain prescriber certification and the Patient Agreement Form. *See* FDA MSJ 18-23.

Plaintiffs claim that FDA's retention of these ETASU must be flawed because Korlym does not have a REMS. Pl. Opp'n 27-28. The comparison is inapt. Korlym is used by patients with Cushing's syndrome, who are "unlikely to be pregnant." DEAR22, 28; *see generally* DEAR16-30. Further, the labeling for Korlym includes the instruction that pregnancy must be excluded before prescribing the drug. That matters because some risks of Mifeprex and its generic—including those relating to heavy bleeding, missed ectopic pregnancy,[4] and other issues—arise from use by

[4] Mifepristone does not cause ectopic pregnancy. But a woman with an undiagnosed ectopic pregnancy may take Mifeprex or its generic and believe she has had a successful abortion, when in fact she is experiencing a ruptured ectopic

pregnant women. Contrary to Plaintiffs' mischaracterization, FDA did not argue that abortion is a "serious side-effect or risk" of Mifeprex or its generic. Pl. Opp'n 28.

Plaintiffs provide no support for their suggestion that composition and dosage are the only factors FDA could consider when comparing Korlym to Mifeprex and its generic. Based solely on those factors, Plaintiffs argue that if Korlym is not "'inherently' toxic or harmful," then Mifeprex and its generic cannot be either. Pl. Opp'n 28. But that misstates the statutory standard. To qualify for a REMS with ETASU, a drug must have "inherent toxicity or potential harmfulness." 21 U.S.C. § 355-1(f)(1). Under the rule of the last antecedent, "inherent" modifies "toxicity" and "potential" modifies "harmfulness." *Lockhart v. United States*, 577 U.S. 347, 351-52 (2016). Thus, a drug may be either "inherently toxic" or "potentially harmful." There is no requirement that it be "inherently harmful"—or, under Plaintiffs' awkward construction, "inherently potentially harmful."

Plaintiffs' remaining arguments (Pl. Opp'n 26-27, 29-33) suffer from the same

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pregnancy, a medical emergency that requires immediate surgical intervention. *See* 2021 REMS 001574 note e (noting that the symptoms of medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy).

flaw: they incorrectly put the onus on FDA to re-justify the ETASU *de novo*. *See* Pl. Opp'n 26-27 (accusing FDA of "reimpos[ing] ETASU" without "point[ing]" to "evidence" affirmatively proving that the ETASU are necessary); *id*. 29-31 (putting the burden on FDA to identify evidence demonstrating the necessity of prescriber certification); *id*. 31-32 (same for Patient Agreement Form); *id*. 32-32 (arguing that FDA's "flawed decision to reimpose" prescriber certification "cannot justify" pharmacy certification). But during the 2021 review, FDA was not required to reexamine all previous REMS decisions (decisions which Plaintiffs do not challenge). Rather, as FDA reasonably explained for each ETASU, it decided not to depart from prior determinations because objective safety information did not justify doing so.

Plaintiffs disagree with FDA's assessments, but disagreement alone does not suffice to invalidate agency action under the APA. *Alaska Cntr. for the Envt. v. West*, 157 F.3d 680, 685 (9th Cir. 1998). "It is well-established that FDA's 'judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference.'" *Cumberland Pharm. Inc. v. FDA*, 981 F. Supp. 2d 38, 48 (D.D.C. 2013) (quoting *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995)). As the Chief Justice admonished the last time a district court ordered FDA not to enforce a mifepristone ETASU, the "significant deference" due to the agency in this area should make

courts reluctant to "compel the FDA to alter the regimen for medical abortion." *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring in the grant of application for stay).

## IV. No Fifth Amendment Rights Are At Issue

The Fifth Amendment claims fail because States have no Fifth Amendment rights. *South Carolina v. Katzenbach*, 383 U.S. 301, 323-24 (1966). Plaintiffs resist that conclusion, arguing that they "may assert the Fifth Amendment rights of staff and students at the University of Washington." Pl. Opp'n 33 (citing *Washington v. Trump*, 847 F.3d 1151, 1159-60 (9th Cir. 2017)). But the Amended Complaint makes no reference to the Fifth Amendment rights of staff or students at UW. Moreover, Plaintiffs do not explain how Washington (let alone the other Plaintiffs) satisfy the requirements for third-party standing.

Third-party standing "allows a narrow class of litigants to assert the legal rights of others" if the litigants themselves have Article III standing. *Alliance for Hippocratic Medicine*, 602 U.S. at 393. To fall within that narrow class, a plaintiff must have "a close relationship with the person who possesses the right" and there must be "a hindrance to the possessor's ability to protect his own interests." *Sessions v. Morales-Santana*, 582 U.S. 47, 58 (2017). Besides Washington, no Plaintiff could claim any connection whatsoever, much less a "close relationship," with the staff and students at UW. And no Plaintiff, including Washington, attempts

to show those unknown staff and students are hindered from protecting their own interests. Thus, no Plaintiff can bootstrap its way to a Fifth Amendment claim based on third-party standing.[5]

## CONCLUSION

For the foregoing reasons, and the reasons set for in FDA's opening brief, the Court should grant Defendants' Cross-Motion for Summary Judgment.[6]

[5] In any event, as FDA explained in its opening brief, FDA's legitimate interest in protecting public health justifies the mifepristone REMS with ETASU.

[6] The Court should reject Plaintiffs' belated request to enjoin hypothetical future agency action. *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 46 n.1 (D.C. Cir. 2013) (holding that relief under the APA is "limited only to vacating the unlawful action, not precluding future agency decisionmaking"). Any such action would be on the basis of an administrative record that does not yet exist. There is no basis on which to assume that Plaintiffs would be likely to succeed on the merits of any challenge to that unknown hypothetical action. If the Court decides injunctive relief is warranted, Defendants request supplemental briefing on scope to ensure that any relief not go beyond redressing UW's alleged compliance costs. *See supra* p. 7.

May 30, 2025

*/s/ Noah T. Katzen*
NOAH T. KATZEN
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 305-2428
(202) 514-8742 (fax)
Noah.T.Katzen@usdoj.gov

*Counsel for Defendants*

**CERTIFICATE OF SERVICE**

I hereby certify that, on May 30, 2025, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

*/s/ Noah T. Katzen*
NOAH T. KATZEN